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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,238	01/03/2007	Pamela Brown	PB60052	6285
20462 7590 10/19/2007 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			EXAMINER MABRY, JOHN	
			ART UNIT 4133	PAPER NUMBER
			NOTIFICATION DATE 10/19/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/552,238	Applicant(s) BROWN ET AL.	
	Examiner John Mabry	Art Unit 4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7 and 10-12 is/are pending in the application.
4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/8/07, 8/21/06, 2/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-7 are drawn to compounds and pharmaceutical compositions of Formula IA and IB. A further election of single disclosed species is required.
- II. Claim 10 is drawn to a method of treating microbial infections in animals from group I. An election of species is required if this group is chosen.
- III. Claim 11 is drawn to a method of treatment of skin and soft tissue in humans from group I. An election of species is required if this group is chosen.
- IV. Claim 12 is drawn to a process of preparing a compound of Formula IA and IB of group I. An election of species is required if this group is chosen.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The special technical feature corresponding to Group I is a pleuromutilin core structure. Group II is drawn to a method of treating microbial infections in animals as its special technical feature. Group III is drawn to a method of treatment of skin and soft tissue in humans as its special technical feature. Group IV is drawn to a process of preparing a compound of Formula IA and IB as its special technical feature. The groups are not considered equivalent.

There is a significant difference in the between compounds/composition and methods of treating a disease/condition. These treatments of diseases/conditions and compounds/compositions are not considered equivalent.

The special technical feature of this invention is the common core found in Formula IA and IB. This special technical feature, found in Journal Antibiotics, 1976, 29, 923-927 as described by Egger et al (see page 924, compounds no. 38 and 39).

Therefore the above claims, are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a common core structure and the technical features present fail to define a contribution over the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to only one invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

may be traversed (37 CFR 1.143) and (ii) **identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

During a telephone conversation with James Kellerman on October 11, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant further elected the species of Example 1 as set forth in the Specification (page 24, Example 1 found in table and first paragraph at bottom of page).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder Advisory

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" in claims 1, 6 and 7 is a relative term which renders the claim indefinite. The term "derivative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "derivative" does not have a clear limitation. What does Applicant intend by this term?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R1 being phenyl and pyridinyl substituted with

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only -CO₂H, does not reasonably provide enablement for R₁ being all five- and six-membered heteroaryl and aryl rings that are substituted by the following:

to the point of attachment of the sulphur, and wherein R¹ is optionally further substituted by up to four groups independently selected from halogen, (C₁₋₆)alkyl, aryl, aryl(C₁₋₆)alkyl, (C₁₋₆)alkoxy, (C₁₋₆)alkoxy(C₁₋₆)alkyl, halo(C₁₋₆)alkyl, aryl(C₁₋₆)alkoxy, hydroxy, nitro, cyano, azido, amino, mono- and di-N-(C₁₋₆)alkylamino, acylamino, arylcarbonylamino, acyloxy, carbamoyl, mono- and di-N-(C₁₋₆)alkylcarbamoyl, (C₁₋₆)alkoxycarbonyl, aryloxycarbonyl, ureido, guanidino, (C₁₋₆)alkylguanidino, amidino, (C₁₋₆)alkylamidino, sulphonylamino, aminosulphonyl, (C₁₋₆)alkylthio, (C₁₋₆)alkylsulphinyl, (C₁₋₆)alkylsulphonyl, heterocyclyl, heteroaryl, heterocyclyl(C₁₋₆)alkyl and heteroaryl(C₁₋₆)alkyl, or two adjacent ring carbon atoms may be linked by a (C₃₋₅)alkylene chain, to form a carbocyclic ring;

Additionally, the specification while being enabling for R₃ and R₄ being H, does not reasonably provide enablement for R₃ and R₄ being hydroxy or fluorine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The Specification does not provide any support for said variables at R₁, R₃ and R₄ positions. Pages 24-27 of the Specification describe starting materials and methods for synthesis of compounds wherein R₁=phenyl or pyridinyl and R₃ and R₄=H, but does not describe or list any reagents wherein compounds can be used to synthesis compounds where R₁, R₃ and R₄ as listed above.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the

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art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted pleuromutilin compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted pleuromutilin compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological and chemical activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Pages 24-27 of the Specification describes starting materials and methods for synthesis of compounds wherein R1=phenyl or pyridinyl and R3 and R4=H, but does not describe or list any

reagents wherein compounds can be used to synthesis compounds where R1, R3 and R4 as listed above. There is limited evidence in the Specification of the example compounds that only covers no or a small portion of the substituents claimed of formula. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The specification does not provide any support for the synthesis of compounds, wherein R1 being all five- and six- membered heteroaryl and aryl rings that are substituted by the following:

to the point of attachment of the sulphur, and wherein R¹ is optionally further substituted by up to four groups independently selected from halogen, (C₁₋₆)alkyl, aryl, aryl(C₁₋₆)alkyl, (C₁₋₆)alkoxy, (C₁₋₆)alkoxy(C₁₋₆)alkyl, halo(C₁₋₆)alkyl, aryl(C₁₋₆)alkoxy, hydroxy, nitro, cyano, azido, amino, mono- and di-N-(C₁₋₆)alkylamino, acylamino, arylcarbonylamino, acyloxy, carbamoyl, mono- and di-N-(C₁₋₆)alkylcarbamoyl, (C₁₋₆)alkoxycarbonyl, aryloxy, ureido, guanidino, (C₁₋₆)alkylguanidino, amidino, (C₁₋₆)alkylamidino, sulphonylamino, aminosulphonyl, (C₁₋₆)alkylthio, (C₁₋₆)alkylsulphinyl, (C₁₋₆)alkylsulphonyl, heterocyclyl, heteroaryl, heterocyclyl(C₁₋₆)alkyl and heteroaryl(C₁₋₆)alkyl, or two adjacent ring carbon atoms may be linked by a (C₃₋₅)alkylene chain, to form a carbocyclic ring;

and wherein R3 and R4 being hydroxy or fluorine.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it

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clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted pleuromutilin compounds wherein R1=phenyl and R3 and R4=H, which are well documented in the art. So far as the examiner is aware, no substituted pleuromutilin compounds of general formula I wherein R1 equals:

R¹ is a five- or six-membered aryl or heteroaryl ring, wherein R¹ is substituted by a carboxylic acid group that is attached at a position which is not adjacent to the point of attachment of the sulphur, and wherein R¹ is optionally further substituted by up to four groups independently selected from halogen, (C₁₋₆)alkyl, aryl, aryl(C₁₋₆)alkyl, (C₁₋₆)alkoxy, (C₁₋₆)alkoxy(C₁₋₆)alkyl, halo(C₁₋₆)alkyl, aryl(C₁₋₆)alkoxy, hydroxy, nitro, cyano, azido, amino, mono- and di-N-(C₁₋₆)alkylamino, acylamino, arylalkylamino, acyloxy, carbamoyl, mono- and di-N-(C₁₋₆)alkylcarbamoyl, (C₁₋₆)alkoxycarbonyl, aryloxy, ureido, guanidino, (C₁₋₆)alkylguanidino, amidino, (C₁₋₆)alkylamidino, sulphonylamino, aminosulphonyl, (C₁₋₆)alkylthio, (C₁₋₆)alkylsulphonyl, (C₁₋₆)alkylsulphonyl, heterocyclidyl, heteroaryl, heterocyclidyl(C₁₋₆)alkyl and heteroaryl(C₁₋₆)alkyl, or two adjacent ring carbon atoms may be linked by a (C₃₋₅)alkylene chain, to form a carbocyclic ring;

and wherein R3 and R4 being hydroxy or fluorine of any kind have been made or used.

(6) Working Examples: Applicant shows example 1-5 (chart on page 24) but no working examples were shown wherein R1, R3 and R4 equals aforementioned substituents have been made or used of any kind.

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(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1, 2, 3, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Egger et al (Journal of Antibiotics 1976, 29, 923-927).

The instant claims disclose compounds of Formula IA wherein R1=C6H4-2-CO2H, R2=vinyl, and R3 and R4=H.

Scope & Content of Prior Art MPEP 2141.01

Egger et al discloses compounds of Formula IA wherein R1=C6H4-4-CO2H, R2=vinyl, and R3 and R4= H.

Differences between Prior Art & the Claims MPEP 2141.02

Egger differs from instant claims in the positional location of the -CO2H on the phenyl ring: the 2-CO2H-C6H4- versus Applicants' 4-CO2H-C6H4- (see page 924, compound no. 38).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

There is little difference between the –CO₂H substituent being at the 2-position as compared at the 4-position on the claimed structure of formula I. It is well established that position isomers are prima facie structurally obvious even in the absence of a teaching to modify. The isomer is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt*, 208 USPQ 343, 349; *In re Mehta*, 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullyot*, 103 USPQ 185; *In re Norris*, 84 USPQ 459; *Ex. Parte Naito*, 168 USPQ 437, 439; *Ex parte Allais*, 152 USPQ 66; *In re Wilder*, 166 USPQ 545, 548; *Ex parte Henkel*, 130 USPQ 474; *Ex parte Biel*, 124 USPQ 109; *In re Petrzilka*, 165 USPQ 327; *In re Crownse*, 150 USPQ 554; *In re Fouche*, 169 USPQ 431; *Ex parte Ruddy*, 121 USPQ 427; *In re Wiechert*, 152 USPQ 249, *In re Shetty*, 195 USPQ 753; *In re Jones*, 74 USPQ 152, 154. There may be others as well. Thus, said claims are rendered obvious by Dodge et al.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (*Englehardt*) and "Position isomerism is fact of close structural similarity" (*Mehta*, emphasis in the original). Note also *In re Jones*, 21 USPQ2d 1942, which states at 1943 "Particular types or categories of structural similarity without more, have, in past cases, given rise to prima facie obviousness"; one of those listed is "adjacent homologues and structural isomers". Position isomers are the basic form of close "structural isomers." Similar is *In re Schechter and LaForge*, 98 USPQ 144, 150, which

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states "a novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds." Note also *In re Deuel* 34 USPQ2d 1210, 1214 which states, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds...a known compound may suggest its analog or isomers, either geometric (cis v. trans) or position isomers (e.g. ortho v. para)." See also MPEP 2144.09, second paragraph. Further, the reference provides for the ring being substituted in any position.

Pharmaceutically acceptable excipient, diluent, carrier and salts are disclosed in above reference on page 925, second complete paragraph.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Compounds of Formula I are disclosed in the following reference: Egger et al Journal of Antibiotics 1976, 29, 915-922.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

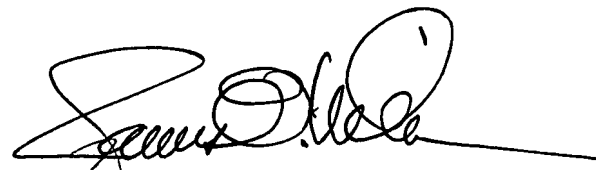
Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JM



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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